

QUANTITY: 12,028 100-tablet btl. at Atlanta, Ga.; Minneapolis and St. Paul, Minn.; Los Angeles, Oakland, San Francisco, Sacramento, and Vernon, Calif.; Chicago, Ill.; Philadelphia, Pa.; Tampa, Fla.; Charleston, W. Va.; New Orleans, La.; Denver, Colo.; Burlington, Des Moines, Cedar Rapids, Ottumwa, and Waterloo, Iowa; Everett and Seattle, Wash.; and Houston, Tex.

SHIPPED: Between 1-13-53 and 10-9-53, from Cleveland, Ohio, by Rhodes Pharmacal Co., Inc.

LABEL IN PART: (Btl.) "Tryptacin Rhodes * * * Tablets."

RESULTS OF INVESTIGATION: Advertisements concerning the use of the article in the treatment of stomach ulcers appeared in various newspapers circulated in the areas where the product was located, but the labeling of the article bore no reference to stomach ulcers.

LIBELED: Between 9-24-53 and 11-10-53, N. Dist. Ga., Dist. Minn., N. Dist. Calif., S. Dist. Calif., N. Dist. Ill., E. Dist. Pa., S. Dist. Fla., S. Dist. W. Va., E. Dist. La., Dist. Colo., N. Dist. Iowa, S. Dist. Iowa, W. Dist. Wash., and S. Dist. Tex.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to state all the conditions or diseases for which the article was intended to be taken, and its labeling failed also to bear adequate directions for use in the treatment of such conditions and diseases.

DISPOSITION: Between 11-6-53 and 8-16-54. 4 seizure actions: Default—destruction. 43 seizure actions: Consent—Claimed by Rhodes Pharmacal Co., Inc., and relabeled.

4643. C-Tone. (F. D. C. No. 36104. S. No. 45-595 L.)

QUANTITY: 27 cases, 12 8-oz. btl. each, at Cambridge, Mass.

SHIPPED: 10-9-53, from New York, N. Y., by Balanced Foods, Inc.

LABEL IN PART: (Btl.) "C-Tone The *Natural* Vitamin C Tonic."

RESULTS OF INVESTIGATION: Prior to the receipt of this shipment, the consignee had distributed to prospective customers a number of circulars entitled "Which of These Dread Killers Threaten Your Advancing Years?" These circulars were identical in text (except for the imprint of consignee) to other circulars concerning this product distributed to various dealers by the shipper of the article.

LIBELED: 11-3-53, Dist. Mass.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use in the treatment of high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, dizzy spells, and for providing energy and improving digestion, which were the conditions and purposes for which the article was intended.

DISPOSITION: 2-21-55. Default—destruction.

4644. Anterior pituitary whole ovarian solution. (F. D. C. No. 37035. S. No. 78-918 L.)

QUANTITY: 14 vials at Dayton, Ohio.

SHIPPED: 1-15-54 and 6-21-54, from Los Angeles, Calif., by American Bio-Chemical Corp.

LABEL IN PART: (Vial) "30 cc Sterile Solution Each cc contains Anterior Pituitary. . . . 25 gr. Whole Ovarian. . . . 55 gr. Chlorobutanol 0.5% Note: There is no scientific evidence available that this product has therapeutic or physiologic activity. For Intramuscular Use Only Caution: Federal law prohibits dispensing without prescription."

LIBELED: 8-6-54, S. Dist. Ohio.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 9-15-54. Default—destruction.

4645. Aqueous extract of anterior pituitary. (F. D. C. No. 37297. S. No. 83-980 L.)

QUANTITY: 26 vials at Kansas City, Mo.

SHIPPED: Between 6-1-52 and 8-13-53, from Kansas City, Mo., by Ashe Lockhart, Inc., to Minneapolis, Minn., and from there reshipped to the consignee's Kansas City office.

LABEL IN PART: (Vial) "10 c. c. Aqueous Extract of Anterior Pituitary Each c. c. contains water soluble extractives from 18½ grains fresh tissue. Contains .5% Chlorobutanol (Chloroform Derivative)."

LIBELED: On or about 10-14-54, W. Dist. Mo.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 12-31-54. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4646. Phenobarbital tablets. (F. D. C. No. 37344. S. No. 77-275 L.)

QUANTITY: 1,100 100-tablet btls. and 1 10,000-tablet tin at Skillman, N. J.

SHIPPED: 10-19-53, from Brooklyn, N. Y., by Robin Pharmacal Corp.

RESULTS OF INVESTIGATION: The tablets had been shipped in bulk; and, upon receipt by the consignee, a number of the tablets were repackaged into bottles.

LIBELED: 11-10-54, Dist. N. J.

CHARGE: 501 (b)—the strength and quality of the article when shipped differed from the standard for phenobarbital tablets set forth in the United States Pharmacopeia since the article failed to meet the test for permissible variations in the weight of individual tablets and some tablets contained more and some tablets contained less than the declared amount of phenobarbital.

DISPOSITION: 12-10-54. Default—destruction.

4647. Triple hormone suspension. (F. D. C. No. 37464. S. No. 63-593 L.)

QUANTITY: 80 vials at Memphis, Tenn.

SHIPPED: 7-19-54, from Chicago, Ill., by Maizel Laboratories.

LABEL IN PART: "10 cc. Vial Intramuscular * * * Triple Hormone Suspension Each cc. Contains: Estradiol 1.2 Mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 77 percent of the labeled amount of estradiol.